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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,471	02/22/2007	Mikiko Kaminuma	IKUTP106US	4357

23623 7590 05/06/2011  
TUROCY & WATSON, LLP  
127 Public Square  
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CLEVELAND, OH 44114

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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05/06/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket1@thepatentattorneys.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/580,471	<b>Applicant(s)</b> KAMINUMA ET AL.	
	<b>Examiner</b> CELIA CHANG	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 March 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28,30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28,30,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/11</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 2, 2011 have been entered and considered carefully.

Claims 1-27, 29, 31, 34 have been canceled. Claims 28, 30, 32-33 are pending.

2. Claims 28, 30, 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous and unclear what is the meets and bounds of the currently amended scope encompassed by "glycine derivative represented by general formula I.

To the extent that the terms includes any chemical modification of formula I to another compound so long the N-C-COO i.e. back bone of glycine is maintain, the claims are still anticipated by Yu et al. US 6,824,786.

It is not unclear whether the term alkyl, alkenyl...etc. are limited to the chain length as specified on p.13-14 or are inclusive of any alkyl, alkenyl, aryl.....etc. If it is intended to encompass the breadth of alkyl, which is a straight or branched carbon chain with one hydrogen being a valence, then the new 112 first and 103(a) will be made.

3. Claims 28, 30, 32-33 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds wherein R1, R2, R3 have chain length of C1-4, does not reasonably provide enablement for the breadth of the claims wherein there is no limitation of the alkyl, alkenyl....etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims.

On p.13 of the specification, the alkyl moieties were particularly named to be C1-4alkyl. The claims provided no limitation of such chain length. Given the broadest interpretation of the scope, the chain length can be those of the naturally occurring fatty acid such as found in Kitano et al. CA 134:285482. Because the compound of CA134 has the utility of good skin feel and less

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skin-irritation, thus, not the same utility as the C1-4 compounds ie. the preferred embodiment of the instant application, the scope of alkyl, etc. without limitation is considered not enabled in absence of factual support.

4. The rejection of claim 1-2, 7-9, 27 now applicable to the amended claims 28, 30, 32-33 under 35 U.S.C. 102(b) over:

(A) Kyowa CA79 or CA93 is maintained for the currently amended claims. Please note that when R1 or @ is aminomethylcargonyl, the compound is glycylglycine.

(B) Yu et al. US 6,824,786, is maintained for the currently amended claims since the compounds are glycine derivatives of the general formula i.e. N-C-COO backbone.

The rejections under 35 USC 102(b) or (e) over JP11-158055; or WO2003/099327 or the pregnant publication US 2005/0152930 are dropped in view of the amendment that R1, R2, R3 cannot be simultaneously hydrogen.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made..

Claims 28, 30, 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-158055 in view of CA131:35667 or Yu et al. US 6,824,786.

**Determination of the scope and content of the prior art ( MPEP §2141.01)**

JP 11-158055 disclosed keratin condition improving composition and an example anticipating the claims was disclosed (see [0011] English translation). Generically, the active ingredients can be amino acid and its derivatives (see claim 1). CA131:35667 provided description of the generic subject matter of the '055 patent that compounds such as tyrosine or trimethylglycine are alternative choice of glycylglycine.

**Ascertainment of the difference between the prior art and the claims ( MPEP §2141.02)**

The difference between the instant claims and the exemplified compound of the JP11-158055 is that instead of the exemplified glycylglycine, the other glycine derivatives was used. CA131 delineated other glycine derivatives are optionally choices for the exemplified species.

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In absent of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

The difference between the instant claims and the exemplified compound of the prior art is the glycine derivative is one of the hydrogen of glycine is derivatized, i.e. an ester when R3 is lower alkyl. Yu et al. taught that a glycine derivative as free acid or ester is an alternative equivalency optional to one having ordinary skill in the art (see col. 9, compounds and examples 3-8 acid as well as lower ester as alternatives)

**Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)**

One having ordinary skill in the art is in possession of the JP 11-158055 reference would find the instant claims prima facie obvious because the instant claims differ from the prior art active compound with one methyl substitution. The replacement of a hydrogen with a methyl group is ordinarily not patentable in absence of unexpected result because such modification is within the sphere of obviousness that surrounds the known compound for its known utility. In re Wood 199 USPQ 137.

Further, such modification would be motivated by the exemplified analogous art of Yu et al. wherein the lower alkyl esters modification in analogous glycine derivative were demonstrated to have analogous activity.

The above references placed glycine and glycine derivatives for keratin condition composition in possession of artisan having ordinary skill. The employment of a lower ester or lower methylated compound of glycine in place of glycine for its conventionally known functionality is prima facie obvious since the motivation to modify and the expectation of success have clearly been suggested by the prior art.

6. Applicants' amendment necessitated the new grounds of rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELIA CHANG, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
May 2, 2011

/Celia Chang/  
Primary Examiner  
Art Unit 1625